I: Claims 1-8, 19, and 20, drawn to polypeptide fragment and the pharmaceutical composition;

II. Claims 9-18, drawn to isolated nucleic acid, vector and host cell;

III. Claims 21-23, 39-53, and 55, drawn to nucleic acid pharmaceutical composition and method of inducing differentiation of fibroblast to myofibroblasts in vivo and in vitro with an effective amount of a nucleic acid;

IV. Claims 24-38 and 54, drawn to the method of inducing differentiation of fibroblast to myofibroblasts in vivo and in vitro with an effective amount of a polypeptide;

V. Claims 56-62, to the method of inducing differentiation of fibroblast to myofibroblasts in vivo and in vitro with an effective amount of an inhibitor of a differentiation-inducing chemokine;

VI. Claims 56, 57, 63, and 64, drawn to the method of inducing differentiation of fibroblast to myofibroblasts in vivo and in vitro with an effective amount of an antibody that specifically binds the CXC chemokine;

VII. Claims 65-68 and 70-72, drawn to a method of screening for an agent comprising detecting the level of protein;

VII. Claims 65-69, 71, and 72, drawn to a method of screening for an agent comprising detecting the level of mRNA;

IX. Claims 73-76, 79, and 80, drawn to a method of prescreening for an agent comprising detecting specific binding of a test agent to a chemokine nucleic acid;

X. Claims 73-75 and 77-80 drawn to a method of prescreening for an agent comprising detecting specific binding of a test agent to a chemokine protein; and

XI. Claims 81-86 drawn to a method of prescreening for an agent said method comprising detecting specific binding of a test agent to a chemokine receptor.

In addition, the Examiner stated that some of the Groups allegedly read on patentably distinct sequences. The Examiner indicated that for an elected Group including claims drawn to an amino acid sequence (e.g., Group I), Applicant must further elect a single amino acid sequence, either "SEQ ID NOS:8 and 9 (IL8) **or** SEQ ID NO:10 (cCAF) **or** SEQ ID NO:11 (MGSA)," Office Action dated January 11, 2002, page 5. The Examiner stated that this is not a species election but a further election of a group.

TRAVERSAL TO RESTRICTION REQUIREMENT

Applicants respectfully point out that the Examiner's requirement for election of a single amino acid sequence within Group I is improper and request that the restriction be withdrawn. First, the Examiner has improperly restricted subject matter within claims (e.g., claims 1-5, 19, and 20), with the result that a single claim must be divided up and presented in several applications. Second, the Examiner has restricted subject matter within Markush claims (e.g., claims 6-8), a practice with does not conform to USPTO restriction practice relating to Markush claims.

The restriction requirement is improper because it restricts subject matter within claims.

The Examiner's statement that the requirement for election of a single amino acid sequence is "not a species election" indicates that the Examiner proposes to not fully examine the generic claims. That is, the Examiner proposes to examine claims that are generic with respect a polypeptide comprising a chemokine fragment only to the extent that the claims read on a single species of amino acid sequence provisionally elected by Applicants, e.g., IL-8. Claim 1, for example, is a generic claim to "a polypeptide comprising a chemokine fragment, wherein said chemokine fragment stimulates differentiation of fibroblasts to myofibroblasts, and wherein said polypeptide does not comprise the full-length, wild-type chemokine." An election of a single amino acid sequence, e.g., IL-8 (SEQ ID NOS:8-9), that is not a species election, would result in an incomplete examination of generic claim 1.

This odd result is a function of the improper restriction of subject matter **within** claims. More specifically, the restriction of claim Group I to the embodiment relating to IL-8, in effect, requires that single claims (*e.g.,* claim 1) be divided up and presented in several applications. Moreover, even if applicants were to file multiple applications, each relating to a different amino acid sequence, such multiple applications would not afford the same protection as generic claim 1.

Requiring restriction within claims flatly contravenes accepted law. As stated by the CCPA:

> As a general proposition, an applicant has a right to have **each claim** examined on the merits.

* * *

> If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.
>
> * * *
>
> §121 provides the Commissioner with the authority to promulgate rules designed to **restrict an application** to one of several claimed inventions . . . . It does not provide a basis under the authority of the Commissioner to **reject** a particular **claim** on that same basis.
>
> * * *
>
> We hold that a rejection under §121 violates the basic right of the applicant to claim his invention as he chooses.

In re Weber, Soder and Boksay, 198 USPQ 328, 331-332 (CCPA 1978) (emphasis added). *See also, In re Haas*, 179 USPQ 623, 624, 625 (CCPA 1973) (*In re Haas I*); *In re Haas*, 198 USPQ 334-337 (CCPA 1978) (*In re Haas II*). **Thus, the CCPA ruled that the statute authorizing restriction practice, *i.e.*, 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim encompasses multiple independently patentable inventions.** *See, In re Weber, Soder and Boksay, In re Haas I, and In re Haas II.* Indeed, the CCPA unequivocally stated that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *Weber*:

> The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim--no matter how broad, which means no matter how many independently patentable inventions may fall within it.

In re Weber, at 334. Applicants respectfully submit that the Examiner's determination that the generic claims of claim Group I should be examined only insofar as they relate to a single amino acid species, e.g., IL-8, is exactly the type of refusal to examine a broad generic claim that *Weber* clearly rejects. As the Patent Office is bound to follow the precedent of the Federal Circuit and its predecessor, the CCPA, Applicants respectfully submit that the restriction of claim Group I to

a single amino acid species, e.g., IL-8, must be withdrawn and such withdrawal is respectfully requested.

A species election requirement may be legally proper for when handling generic claims.

Although restriction within a single claim is legally improper, the Patent Office is not required, at least initially, to specifically examine every species encompassed by a generic claim. The procedure for handling applications that include generic claims is set forth in 37 CFR § 1.146. This rule provides that "[i]n the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted **if no claim to the genus is found to be allowable**." As stated in MPEP § 809.02(a), "[u]pon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141." Thus, where generic claims are present, an applicant can be required to elect a species for initial examination, but the generic claims are still subject to examination to determine whether such generic claims are allowable.

Election of species practice strikes an appropriate balance between the interests of the Patent Office in promoting administrative efficiency and avoiding unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. §112 are satisfied. *See, e.g.,* MPEP at 803.02; *In re Wolfrum* 179 USPQ 620 (CCPA, 1973); *In re Kuehl* 177 U.S.P.Q. 250 (CCPA, 1973). Unlike a restriction requirement, an election of species requirement does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications that will not capture the full scope of the invention.

In the present case, while a restriction requirement based on a single amino acid sequence type is clearly legally improper, an election of species requirement would not be improper. If the Examiner decides to withdraw the single amino acid sequence restriction requirement, and instead require an election of species, Applicants provisionally elect the species drawn to IL-8. The claims reading on the elected species are 1-8, 19, and 20.